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K072119
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CardinalHealth

Cardinal Health
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SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Airlife Nebulizer Cap

Sponsor:	Cardinal Health 1430 Waukegan Road MPKB McGaw Park, IL 60085
Regulatory Affairs: Contact	Sharon Nichols
Telephone:	(847) 578-6610
Date Summary Prepared:	May 2007
Common Name:	Airlife Nebulizer Cap
Classification Name:	Nebulizer (Direct Patient Interface)
Classification:	Class II per 21CFR §868.5630
Predicate Device:	Airlife Nebulizer Cap, K962161 Nebulizer with Air Entrainment and Immersion Heater Adapter, K801251
Description:	A nebulizer cap deliver an aerosol of oxygen, air, and either water or saline. It consists of a dry device attached to a bottle of sterile solution. In use, the device attaches to a 50 psi source of oxygen, which is regulated by a flow meter. An air entrainment dial regulates airflow to adjust for desired oxygen concentration. The outlet port attaches to 22 mm corrugated tubing, which acts as a conduit for the aerosol to the patient.

Intended Use:	The Nebulizer cap is for use with Sterile Water or Saline for Inhalation, USP in 500 ml and 1000 ml, and 1500 ml bottles for inhalation therapy only.
Substantial Equivalence:	The Airlife Nebulizer Cap is substantially equivalent to the Airlife Nebulizer Cap in that: - the intended use is the same - the performance attributes are the same
Summary of Technological Characteristics:	The proposed device and the predicate device are composed of the same or similar design, materials and the manufacturing characteristics.
Summary of testing:	All materials used in the fabrication of the Airlife Nebulizer Cap were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.
Non-Clinical Testing:	Performance testing demonstrated that the proposed device is substantially equivalent to the currently marketed Nebulizer Cap with regard to functional characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2007

Cardinal Health
C/O Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K072119
Trade/Device Name: Airlife Nebulizer Cap
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: July 31, 2007
Received: August 1, 2007

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):	Unknown at this time
Device Name:	Airlife Nebulizer Cap
Indications For Use:	The Nebulizer cap is for use with Sterile Water or Saline for Inhalation, USP in 500 ml, 1000 ml, and 1500 ml bottles for inhalation therapy only.

Prescription Use X or Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) acting BC.
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072119